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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,582	07/01/2003	Rajneesh Taneja	6951.US.O2	5225

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ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER

HAWES, PILI ASABI

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/611,582	Applicant(s) TANEJA, RAJNEESH	
	Examiner Pili A. Hawes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01-12-2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 1-12-2004 is acknowledged. Claims 1-8 are pending in this action. Claims 1-8 are rejected.

Claim Objections

Claims 1 and 8 are objected to because of the following informalities: the instant claims recite PPI but do not spell out what is meant by PPI. Examiner suggests spelling out PPI to say proton pump inhibitor in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 7 are rejected under 35 U.S.C. 102(a) and 102 (e) as being anticipated by WO 02/45692.

WO '692 discloses compositions comprising acid labile drugs, specifically proton pump inhibitors in a suspension to be administered to a patient in need thereof. The reference teaches adding inorganic basic salts (page 6). Among the proton pump inhibitors listed was lansoprazole (page 1, and example 6, page 13). The dosage form is in the form of a powder and prior to administration the active agent is combined with the liquid vehicle (page 3). Example C discloses the composition is suspended in purified water. Water is a liquid vehicle with a pH of greater than 6.5. As a suspension is formed in Example C then it is the position of the examiner that the composition has a viscosity sufficient to form a suspension.

Claims 1-3, 7 and 8 are rejected under 35 U.S.C. 102(b) as being unpatentable over WO 94/25070.

WO '070 teaches a pharmaceutical composition for oral administration to animals comprising a proton pump inhibitor in the form of beads that are enterically coated and incorporated with a pH buffer into water or a water solution (claim 6). Water is a liquid

Art Unit: 1615

vehicle that has a pH greater than 6.5. The suitable pH buffers are used to improve the functional stability of the composition (page 8). The proton pump inhibitor is lansoprazole (claim 11). The reference also teaches making a kit comprising the dry enteric coated beads (claims 14, 15), and the enterically coated beads are added to a liquid vehicle, such as water.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1615

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/45692.

WO '692 discloses compositions comprising acid labile drugs, specifically proton pump inhibitors in a suspension to be administered to a patient in need thereof. The reference teaches adding inorganic basic salts (page 6). Among the proton pump inhibitors listed was lansoprazole (page 1, and example 6, page 13). The dosage form is in the form of a powder and prior to administration the active agent is combined with the liquid vehicle (page 3). Example C discloses the composition is suspended in purified water. Water is a liquid vehicle with a pH of greater than 6.5. As a suspension is formed in Example C then it is the position of the examiner that the composition has a viscosity sufficient to form a suspension. The reference also teaches making different dosage forms with different dosage amounts of the active agent (page 10). Thus it would have been obvious to one of ordinary skill in the art to make a dosage form that comprises two doses of the proton pump inhibitor.

Although the reference does not teach the specific viscosity requirement it would be obvious to one of ordinary skill in the art to adjust the thickening ingredients in the composition to achieve the desired viscosity.

The reference does not specifically disclose a kit composition. However it does disclose first making the microgranules and then adding them to a liquid vehicle. It would have been obvious to one of ordinary skill in the art that the two components, the

Art Unit: 1615

microgranules and the liquid vehicle would first need to be in separate containers before they are mixed. Thus a kit comprising two separate containers, one comprising the microgranules of acid labile active agent (proton pump inhibitor) and the other the liquid vehicle would be obvious to one of ordinary skill in the art.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/25070.

WO '070 teaches a pharmaceutical composition for oral administration to animals comprising a proton pump inhibitor in the form of beads that are enterically coated and incorporated with a pH buffer into water or a water solution (claim 6). Water is a liquid vehicle that has a pH greater than 6.5. The suitable pH buffers are used to improve the functional stability of the composition (page 8). The proton pump inhibitor is lansoprazole (claim 11). The reference also teaches making a kit comprising the dry enteric coated beads (claims 14, 15), and the enterically coated beads are added to a liquid vehicle, such as water.

The reference does not teach the viscosity requirement.

One of ordinary skill in the art would be motivated to make a solution with a viscosity that is suitable to form a suspension. One of ordinary skill in the art would know how to add thickening agents and other ingredients to achieve the desired viscosity.

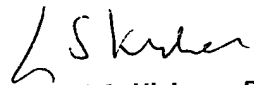
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615


Soilamudi S. Kishore, PhD
Primary Examiner
Group 1600